

JUN 17 2008

K080297
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510(K) SUMMARY

OFFICIAL CONTACT: Troy A. Jack
Sr. Regulatory Affairs Specialist
MEDRAD, Inc.
One MEDRAD Drive
Indianola, PA 15051
(412) 767-2400 ext. 3305

CLASSIFICATION NAME: Infusion Pump

COMMON NAME(S): PET Infusion System

PROPRIETARY NAME: MEDRAD Intego™ PET Infusion System

PREDICATE DEVICES:

- MEDRAD Continuum MR Infusion System (K032771)
- Cal/Rad Mark VI/VDC-05 Dose Calibrator, Model 34-165 (K030066)
- Personnel Protective Shield (Class I exempt)
- Radionuclide Rebreather System (Class II)
- MEDRAD Avanta Fluid Management Injection System [Patient Administration Set] (K050456)

INTENDED USE: The MEDRAD Intego PET Infusion System is intended to deliver accurate doses of ¹⁸F Fluorodeoxyglucose (FDG) radiopharmaceuticals and commonly used flushing solutions to patients during molecular imaging (nuclear medicine) diagnostic procedures. The MEDRAD Intego PET Infusion System is also intended to provide effective radiation shielding to medical personnel from Fluorine-18 (¹⁸F) radiation exposure during nuclear medicine diagnostic procedures.

CONTRAINDICATIONS: This device should not be used for pediatric patients.

DEVICE DESCRIPTION: The MEDRAD Intego PET Infusion System is a self-contained, shielded mobile cart. FDG is stored within a shielded chamber within the body of the MEDRAD Intego PET Infusion System in a bulk container until the time of the infusion. A multi-patient Source Administration Set (SAS) is installed within the shielded chamber at the same time a new bulk container of FDG is installed. Just prior to an infusion, the MEDRAD Intego PET Infusion System measures a dosage of FDG and a volume of saline flush in the dose calibrator. Once the correct radiation level is achieved, the dose of FDG / saline is injected into the patient via a disposable patient administration set.

This infusion system fulfills the following clinical needs:

- a. Dispense accurate doses of ^{18}F Fluorodeoxyglucose (FDG) radiopharmaceuticals and commonly used flushing solutions to patients during nuclear medicine diagnostic procedures.
- b. Provide effective radiation shielding to medical personnel from Fluorine-18 (^{18}F) radiation exposure during nuclear medicine diagnostic procedures.

The MEDRAD Intego PET Infusion System meets the following performance requirements:

- a. For a typical 15 mCi infusion per patient, ^{18}F radiation exposure for medical personnel will be less than 6 mRem finger dose and 0.3 mRem whole body dose.
- b. Flexibility to program the required dose either by activity only or by activity per patient weight.
- c. Ability to deliver ^{18}F radiopharmaceuticals within +/- 10% of the prescribed dose and within +/- 2% of the measured dose, excluding ionization chamber calibration factor.
- d. Capability to retain and print infusion history and dispensing records



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2008

Mr. Troy A. Jack
Senior Regulatory Affairs Specialist
Medrad, Inc.
One Medrad Drive
INDIANOLA PA 15051-0780

Re: K080297

Trade/Device Name: MEDRAD Intego™ PET Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: II
Product Code: FRN
Dated: May 1, 2008
Received: May 2, 2008

Dear Mr. Jack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

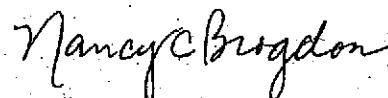
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080297

Device Name: MEDRAD Intego™ PET Infusion System

Indications for Use: The MEDRAD Intego™ PET Infusion System is intended to deliver accurate doses of ¹⁸F Fluorodeoxyglucose (FDG) radiopharmaceuticals and commonly used flushing solutions to patients during molecular imaging (nuclear medicine) diagnostic procedures. The MEDRAD Intego™ PET Infusion System is also intended to provide effective radiation shielding to medical personnel from Fluorine-18 (¹⁸F) radiation exposure during nuclear medicine diagnostic procedures.

Prescription Use _____
(Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

John M. Young Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K080297